

## REMARKS

Claims 34-43 were rejected and remain pending. In light of the following remarks, Applicant respectfully requests reconsideration and allowance of claims 34-43.

### Interview Summary

Applicant's agent thanks Examiner Nguyen for the courtesy of the telephonic interview conducted July 11, 2005. The substance of that telephonic interview involved a discussion of the rejection and arguments presented herein.

### Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 34-43 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, alleging that there "is literally no support" in Applicant's specification for the present claims.

Applicant respectfully disagrees. The test for determining compliance with the written description requirement is whether the disclosure of an application describes the invention so that one skilled in the art reasonably can conclude that the inventor had possession of the claimed invention at the time of filing. *See, e.g., Vas-Cath, Inc. v. Mahhurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). The Federal Circuit recently clarified the written description test, cautioning that:

Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is secondary to the statutory mandate that "[t]he specification shall contain a written description of the invention"

*Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 285 F.3d 1013, 62 USPQ2d 1289 (Fed. Cir. 2002).

In the same case, the Federal Circuit reaffirmed the holding that "the written description requirement is satisfied by the patentee's disclosure of 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.'" *Id.*

(citing *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed.Cir.1997)).

In addition, to comply with the written description requirement, the specification “need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed.” *Eiselstein v. Frank*, 52 F.3d 1035, 1038, 34 USPQ2d 1467 (Fed.Cir.1995) (citing *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1562, and *In re Wertheim*, 541 F.2d 257, 265 (CCPA 1976)). In fact, after indicating that there is no *in haec verba* requirement, the MPEP states that newly added claim limitations need to be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163.

A person having ordinary skill in the art reading Applicant’s specification would have understood that Applicant invented the presently claimed subject matter. This is particularly true given that Applicant’s specification discloses that heart valve cells expressing polypeptides with nitric oxide synthase activity do not exhibit characteristics indicative of heart valve degeneration. *See, e.g.*, page 2, lines 12-14. In addition, Applicant’s specification discloses that heart valve cells expressing polypeptides with nitric oxide synthase activity exhibit, in response to a valvular heart disease-promoting stimulus, less proliferation. *See, e.g.*, page 2, lines 20-23. Applicant’s specification also discloses that inhibitors (*e.g.*, hydroxymethylglutaryl coA reductase inhibitors) can slow the onset of heart valve degeneration. *See, e.g.*, page 16, line 5 to page 17, line 1. In particular, Applicant’s specification discloses that administration of inhibitors can increase nitric oxide synthase activity within valvular tissue and inhibit heart valve cell proliferation normally induced by harmful stimuli. *See, e.g.*, page 16, lines 22-27. Taken together, a person having ordinary skill in the art reading Applicant’s specification including these sections would have appreciated that both nitric oxide synthase activity and heart valve cell proliferation are involved in heart valve degeneration. In fact, a person having ordinary skill in the art reading Applicant’s specification would have appreciated that both increased nitric oxide synthase activity and decreased heart valve cell proliferation can contribute to reducing heart valve degeneration. Moreover, Applicant’s specification discloses assessing the effects of pravastatin on heart valve

degeneration in Example 2. *See*, page 22. Specifically, Applicant's specification discloses measuring both nitric oxide synthase activity and proliferation. *See*, page 23, lines 9-15 and page 24, lines 3-11, respectively. Thus, a person having ordinary skill in the art reading Applicant's specification would have appreciated that claims 34-43 reflect what Applicant's specification discloses has been invented. Thus, Applicant's specification fully supports claims 34-43.

In light of the above, Applicant respectfully requests withdrawal of the Examiner's rejection of claims 34-43 under 35 U.S.C. § 112, first paragraph.

### CONCLUSION

Applicant submits that claims 34-43 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone number below if such will advance prosecution of this application. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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